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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,626	08/05/2003	Gregory M. Glenn	056707-5009-01	6381

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,626	GLENN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 98-146 are pending.

2. In view of Applicants' amendment and remark and cancellation of claims in copending applications, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 141-143 (previously claims 91-94) stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicants' arguments filed on 5/3/07 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the support can be found on p. 26 of the instant application.

However, the specification does not disclose the particular combination of sucrose and trehalose as recited or the particular number of sugars being present in the formulation. The mere description of sugars is not sufficient for the written description of particular numbers and a specific combination of sugars.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 98-146 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 257-362 of copending Application No. 10/790,715, claims 50-59 of copending Application No. 11/334,349, claims 70-97 of copending Application No. 11/141,690. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '715, '349 and '690 applications teach a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in dry form. The '715, '349 and '690 applications further teach various antigens being anthrax, influenza antigen or rabies virus, various adjuvant being DNA, cytokines, bacterial ribosylating exotoxins or tumor necrosis factor alpha. The '715, '349 and '690 applications teaches the formulation is applied to skin with an occlusive dressing or through a patch.

Applicants' arguments and Declaration by Robert Seid filed on 5/3/07 have been fully considered but they were not persuasive.

Applicants trarversed the rejection based on the declaration by Robert Seid that the copending applications are not variant of the claimed invention.

However, the '715, '349 and '690 applications teaches the formulation is applied to skin with an occlusive dressing or through a patch and the declaration by Gregory Glenn filed on 10/10/06 set forth placing patch as administering "dry formulation" to induce the immune response.
Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '715, '349 and '690 applications teach a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in form of "patch". Moreover, the instant application discloses the antigen and the adjuvant can be the same molecule and it reads on the '349 application as it discloses "an antigen only".

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

7. Claims 98-135 are provisionally rejected under judicially created doctrine of double patenting over claims 125-128 of copending Application No. 11/516,462 and claims 121-148 of copending Application No. 11/109,948. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicants' arguments and Declaration by Robert Seid filed on 5/3/07 have been fully considered but they were not persuasive.

Applicants trarversed the rejection based on the declaration by Robert Seid that the copending applications are not variant of the claimed invention.

However, the '462 and '948 applications teaches the formulation is applied to skin with an occlusive dressing or through a patch and the declaration by Gregory Glenn filed on 10/10/06 set forth placing patch as administering "dry formulation" to induce the immune response.

In light of the discussion in section 6 above, the nonstatutory double patenting rejection is maintained.

8. The following new rejection is necessitated by Applicants' addition of new claims filed on 5/3/07.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 100, 117 and 119 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the claims as originally filed do not provide a written description for a phrase " nucleic acid" as in claim 100 and a phrase " binding B subunit of a bARE, a toxoid of a bARE" as in claims 117 and 119.

The phrase " nucleic acid" as in claims 100 in the context of antigen and/or adjuvant is not supported in the originally filed claims and the specification. The specification on p. 7-8 as Applicants provided discloses the nucleic acid in terms of genetic immunization wherein the genetic immunization drawn to administering of "plasmid DNA" which encodes protein of interest in a subject. However, the citation of "nucleic acid" encompasses RNA, siRNA or other forms of DNA which are not involved in genetic immunization.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 98-146 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 123-162 of copending Application No. 11/143,942. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '942 application teaches a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in dry form. The '942 application further teaches various antigens being anthrax, influenza

antigen or rabies virus, various adjuvant being DNA, cytokines, bacterial ribosylating exotoxins or tumor necrosis factor alpha. The '942 application teaches the formulation is applied to skin with an occlusive dressing or through a patch (dry formulation). As the instant application teaches the antigen and the adjuvant are the same molecule, it reads on the '942 application wherein the formulation comprises "an antigen" only.

13. The following rejection is reinstated upon further consideration of declaration by Dr. Gregory Glenn filed on 10/10/06.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 98-146 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling a method of inducing an immune response by applying a formulation onto pretreated (mechanically or chemically disrupted or hydrated) skin, does not reasonably provide enablement for a method of inducing an immune response by applying a dry formulation onto skin of a subject which encompasses dry or intact. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)).

The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

There is insufficient guidance in the specification as filed as to how the skilled artisan would use the dry formulation comprising an antigen and adjuvant to skin to induce immune response to achieve the intended use of the claimed invention without undue experimentation.

As disclosed in the specification of instant application, p. 32-52, examples 1-7, the working examples and data which shown induced immune responses are either pretreated with aqueous media or applying antigen/adjuvant formulation in aqueous form. As seen on Table 3, no immune response was induced without pretreatment of skin and powder form of antigen.

Furthermore, the specification does not reasonably provide enablement for a method of inducing an immune response without any forms of pre-treatment to break the skin. In order to induce an antigenic specific immune response transcutaneously, one must break skin with abrasive or chemical penitration, or hydration and occlusion to disrupt natural, physical and chemical barrier of skin. The skin serves physical and anatomic barriers that prevent entry of pathogens (Kuby, 2000, Immunology, 4th Ed, p. 7, 8, 57, of record).

The Declaration by Dr. Gregory Glenn filed on 10/10/06 has been fully considered but it was not persuasive.

In section 4 of Declaration, 50ug LT "dry patch" was placed on the skin of patients without any pretreatment, shaving of any manipulation. However, the patch used in the experiment was not fully described how the patch was made, prepared and administered in terms of materials, compositions in formulation and method of administration to the patients.

As in the p.27 of the instant application, the materials used to make patch and the formulation comprised in the patch includes AQUAPHOR, COMFEEL or TEGADERM and they includes wax, oil, panthenol and plastic adhesive means. The ingredients for those patches provide penetration enhancement upon administration of the formulation onto skin, having the plastic adhesive means provides hydration means whiling wearing the patch for prolonged time (e.g. 6 hours as in the experiment in the Declaration) and the skin perspires. The plastic adhesive of patch upon removal is abrasive. Therefore, the administration of the antigenic formulation is not in the dry form and the application via patch provides concurrent pretreatment of skin until the removal of patch. Due to the lack of information on how the patch and the

formulation was prepared, and how the experiments conducted, it is not convincing the immune response by dry antigenic formulation can be induced without pretreating of skin.

Thus, Applicant has not provided any guidance to enable one skill in the art to use claimed invention in manner reasonably correlated with the scope of enablement. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

16. No claims are allowable.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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July 18, 2007

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